

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Awadwesh K. Mishra		
SERIAL NUMBER:	09/321,766	EXAMINER:	Edward J. Webman
FILING DATE:	May 28, 1999	ART UNIT:	1617
CUSTOMER No.:	35437	CONFIRMATION No.	7018
FOR:	THERMOPROTECTED COMPOSITIONS AND PROCESS FOR TERMINAL STEAM STERILIZATION OF MICROPARTICLE PREPARATIONS		

**Mail Stop Amendment**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants hereby make of record the documents listed on the attached modified Form PTO-1449, as well as copies of the listed documents.

This Information Disclosure Statement is being filed after the mailing date of a first Office Action on the merits, and, accordingly, a fee of \$180.00 as set forth in 37 C.F.R. §1.17(p) is enclosed.

It is respectfully requested that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims. The Examiner is also respectfully requested to sign and date the enclosed Form PTO-1449 to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.

By submitting this Supplemental Information Disclosure Statement, the Applicants make no representation that: (1) a search has been performed, of the extent of any search performed, or that more relevant information does not exist; (2) the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b); and (3) the

11/29/2004 BABRAHA1 00000068 09321766

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180.00 OP

NYC 306342v1

Applicant: Awadhesh K. Mishra  
U.S. Serial No.: 09/321,766  
Filing Date: May 28, 1999

Attorney Docket No.: 28069-523  
(Formerly: 121-176)

information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

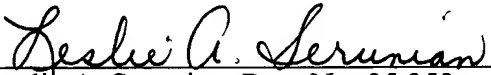
The order of presentation of the references should not be construed as an indication of the importance of the references. The Examiner is urged to form his/her own conclusion regarding the relevance of the cited information.

Please charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. **50-0311**, Reference No. **28069-523**, Customer No. **35437**.

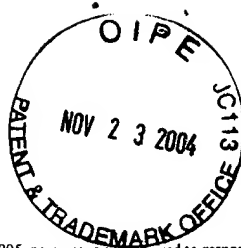
Respectfully submitted,

MINTZ LEVIN COHN FERRIS GLOVSKY  
& POPEO, P.C.

Date: November 23, 2004

  
Leslie A. Serunian, Reg. No. 35,353  
MINTZ, LEVIN, COHN, FERRIS  
GLOVSKY & POPEO, P.C.  
The Chrysler Center  
666 Third Avenue, 24<sup>th</sup> Floor  
New York, New York 10017  
Tel: (212) 935-3000  
Fax: (212) 983-3115

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PTO/SB (12-97)

OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>Modified Form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)	Application Number	09/321,766
	Filing Date	May 28, 1999
	First Named Inventor	Awadhesh K. MISHRA
	Group Art Unit	1617
	Examiner Name	E.J. Webman
	Attorney Docket Number	28069-523

U.S. PATENT DOCUMENTS							
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	A	5,091,187 A	Feb. 25, 1992	Duncan H. Haynes et al.			

FOREIGN PATENT DOCUMENTS							
Exam Initials	Cite No.	Foreign Patent Document Office	Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes	No
	B1	WO	98/07414	Research Triangle Pharmaceuticals	Feb. 26, 1998		
	B2	DE	4440337 A	DDS Drug Delivery Services GES (German priority document of U.S. Patent No. 5,858,410, of record)	May 15, 1996		X

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.	
	C	Copy of International Search Report for corresponding PCT International Application No. PCT/US99/11888. (3 sheets).	
Examiner Signature		Date Considered	

EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.



Attorney Docket No. 401730/SKYE PHARMA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

AWADHESH K. MISHRA

Application No. 09/321,766

Filed: May 28, 1999

Group Art Unit: 1617

Examiner: E.J. Webman

For: THERMOPROTECTED  
COMPOSITIONS AND PROCESS FOR  
TERMINAL STEAM STERILIZATION  
OF MICROPARTICLE  
PREPARATIONS

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, D.C. 20231

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

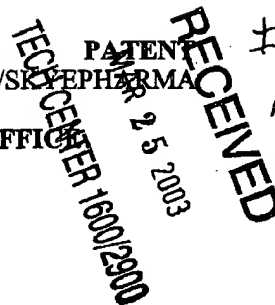
The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☐ within any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date



of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

- ☒ after (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:

☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).

or

☒ the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).

- ☐ after the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

- ☐ after the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

#### Copies of the References

- ☒ Copies of the references listed on the enclosed Form 1449 are enclosed herewith. Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3).

- ☐ A copy of the foreign search report is enclosed herewith.

- ☐ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		Status (check one)		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

**Statement under 37 CFR 1.97(e)**

- ☐ The undersigned hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The undersigned hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

**Statement under 37 CFR 1.704(d)**

- ☐ The undersigned hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

**Fees**

- ☐ No fee is owed by the applicant(s).
- ☒ The IDS Fee of \$180 under 37 CFR 1.17(p) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$.
- ☒ Charge Deposit Account No. 12-1216 in the amount of \$180.00.

**Authorization to Charge Additional Fees**

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

**Instructions as to Overpayment**

In re Appln. of AWADHESH K. MISHRA  
Application No. 09/321,766

**Instructions as to Overpayment**

☒ Credit Account No. 12-1216.  
☐ Refund

Respectfully submitted,


*Xavier Pillai*

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Xavier Pillai, Reg. No. 39,799  
LEYDIG, VOIT & MAYER, LTD.  
700 Thirteenth Street, N.W., Suite 300  
Washington, DC 20005-3960  
(202) 737-6770 (telephone)  
(202) 737-6776 (facsimile)

Date: 3/21/03

IDS (Rev. 4/19/2002)

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
Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete If Known</b>	
				Application Number	09/321,766
				Filing Date	May 28, 1999
				First Named Inventor	Awadhes K. MISHRA
				Group Art Unit	1617
				Examiner Name	E. J. Webman
Sheet	1	of	8	Attorney Docket Number	401730/SKYEPhARMA

U.S. PATENT DOCUMENTS						
Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	1	2803582		Cherney	8/20/1957	
	2	3137631		Soloway	6/16/1964	
	3	3216897		Krantz, Jr.	11/9/1965	
	4	3274063		Nieper et al.	9/20/1966	
	5	3594476		Merrill	7/20/1971	
	6	3715432		Merrill	2/6/1973	
	7	3755557		Jacobs	8/28/1973	
	8	3794476		Michalik et al.	2/26/1974	
	9	3937668		Zolle	2/10/1976	
	10	3960757		Morishita et al.	6/1/1976	
	11	3965255		Bloch et al.	6/22/1976	
	12	4016100		Suzuki et al.	4/5/1977	
	13	4053585		Allison et al.	10/11/1977	
	14	4056635		Glen et al.	11/1/1977	
	15	4073943		Wretlind et al.	2/14/1978	
	16	4078052		Papahadjopoulos	3/7/1978	
	17	4089801		Schneider	5/16/1978	
	18	4102806		Kondo et al.	7/25/1978	
	19	4107288		Oppenheim et al.	8/15/1978	
	20	4133874		Miller et al.	1/9/1979	
	21	4145410		Sears	3/20/1979	
	22	4147767		Yapel, Jr.	4/3/1979	
	23	4186183		Steck et al.	1/29/1980	
	24	4219548		Reller	8/26/1980	
	25	4235871		Papahadjopoulos et al.	11/25/1980	
	26	4241046		Papahadjopoulos et al.	12/23/1980	
	27	4271196		Schmidt	6/2/1981	
	28	4298594		Sears et al.	11/3/1981	
	29	4302459		Steck et al.	11/24/1981	
	30	4308166		Marchetti et al.	12/29/1981	
	31	4309421		Ghyczy et al.	1/5/1982	
	32	4316884		Alam et al.	2/23/1982	
	33	4320121		Sears	3/16/1982	
	34	4325871		Sasaki et al.	4/20/1982	
	35	4328222		Schmidt	5/4/1982	
	36	4329332		Couvreur et al.	5/11/1982	
	37	4331654		Morris	5/25/1982	
	38	4332795		Ghyczy et al.	6/1/1982	
	39	4332796		Los	6/1/1982	

Examiner Signature		Date Considered	
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- \* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).
- + An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).



Please type a plus sign (+) inside this box → 


Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	09/321,766
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				First Named Inventor	Awadhesh K. MISHRA
				Group Art Unit	1617
Examiner Name	E. J. Webman				
Sheet	2	of	8	Attorney Docket Number	401730/SKYEPhARMA

U.S. PATENT DOCUMENTS						
Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date if Appropriate
		Application or Patent Number	Kind Code			
	40	4340594		Mizushima et al.	7/20/1982	
	41	4345588		Widder et al.	8/24/1982	
	42	4351831		Growdon et al.	9/28/1982	
	43	4356167		Kelly	10/26/1982	
	44	4369182		Ghyczy et al.	1/18/1983	
	45	4371516		Gregory et al.	2/1/1983	
	46	4378354		Ghyczy et al.	3/29/1983	
	47	4394372		Taylor	7/19/1983	
	48	4397846		Weiner et al.	8/9/1983	
	49	4411894		Schrank et al.	10/25/1983	
	50	4411933		Samejima et al.	10/25/1983	
	51	4421747		Ghyczy et al.	12/20/1983	
	52	4427649		Dingle et al.	1/24/1984	
	53	4432975		Libby	2/21/1984	
	54	4448765		Ash et al.	5/15/1984	
	55	4483847		Augart	11/20/1984	
	56	4485054		Mezei et al.	11/27/1984	
	57	4492720		Mosier	1/8/1985	
	58	4515736		Deamer	5/7/1985	
	59	4529561		Hunt et al.	7/16/1985	
	60	4532089		MacDonald	7/30/1985	
	61	4610868		Fountain et al.	9/9/1986	
	62	4613505		Mizushima et al.	9/23/1986	
	63	4622219		Haynes	11/11/1986	
	64	4675236		Ohkawara et al.	6/23/1987	
	65	4687762		Fukushima et al.	8/18/1987	
	66	4725442		Haynes	2/16/1988	
	67	4756910		Yagi et al.	7/12/1988	
	68	4758598		Gregory	7/19/1988	
	69	4761288		Mezei	8/2/1988	
	70	4762720		Jizomoto	8/9/1988	
	71	4766046		Abra et al.	8/23/1988	
	72	4776991		Farmer et al.	10/11/1988	
	73	4800079		Boyer	1/24/1989	
	74	4801455		List et al.	1/31/1989	
	75	4803070		Cantrell et al.	2/7/1989	
	76	4806350		Gerber	2/21/1989	

Examiner Signature		Date Considered	
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\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

Please type a plus sign (+) inside this box → 

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	09/321,766	
			Filing Date	May 28, 1999	
			First Named Inventor	Awadhesh K. MISHRA	
			Group Art Unit	1617	
			Examiner Name	E. J. Webman	
Sheet	3	of	8	Attorney Docket Number	401730/SKYEPhARMA

U.S. PATENT DOCUMENTS						
Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date if Appropriate
		Application or Patent Number	Kind Code			
	77	4806352		Cantrell	2/21/1989	
	78	4826687		Nerome et al.	5/2/1989	
	79	4839111		Huang	6/13/1989	
	80	4880634		Speiser	11/14/1989	
	81	4895726		Curtet et al.	1/23/1990	
	82	4961890		Boyer	10/9/1990	
	83	4963367		Ecanow	10/16/1990	
	84	4973465		Baurain et al.	11/27/1990	
	85	4990337		Kurihara et al.	2/5/1991	
	86	5030453		Lenk et al.	7/9/1991	
	87	5100591		Leclef et al.	3/31/1992	
	88	5164380		Carli et al.	11/17/1992	
	89	5169847		Nagy née Kricsfalussy et al.	12/8/1992	
	90	5179079		Hansen et al.	1/12/1993	
	91	5217707		Szabo et al.	6/8/1993	
	92	5246707		Haynes	9/21/1993	
	93	5272137		Blasé et al.	12/21/1993	
	94	5302401		Liversidge et al.	4/12/1994	
	95	5304564		Tsuboi et al.	4/19/1994	
	96	5320906		Eley et al.	6/14/1994	
	97	5326552		Na et al.	7/5/1994	
	98	5346702		Na et al.	9/13/1994	
	99	5352459		Hollister et al.	10/4/1994	
	100	5364633		Hill et al.	11/15/1994	
	101	5389377		Chagnon et al.	2/14/1995	
	102	5399363		Liversidge et al.	3/21/1995	
	103	5447710		Na et al.	9/5/1995	
	104	5527537		Dietl	6/18/1996	
	105	5545628		Deboeck et al.	8/13/1996	
	106	5552160		Liversidge et al.	9/3/1996	
	107	5560931		Eickhoff et al.	10/1/1996	
	108	5569448		Wong et al.	10/29/1996	
	109	5571536		Eickhoff et al.	11/5/1996	
	110	5576016		Amselem et al.	11/19/1996	
	111	5578325		Domb et al.	11/26/1996	
	112	5589455		Woo	12/31/1996	
	113	5603951		Woo	2/18/1997	
	114	5631023		Kearney et al.	5/20/1997	

Examiner Signature	Date Considered
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+

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**Complete If Known**


Application Number	09/321,766
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Examiner Name	E. J. Webman
Attorney Docket Number	410730/SKYEPhARMA

Sheet	4	of	8
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Date Considered

- A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).
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Please type a plus sign (+) inside this box → 


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				Examiner Name	E. J. Webman
Sheet	5	of	8	Attorney Docket Number	401730/SKYE PHARMA

FOREIGN PATENT DOCUMENTS								
Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No <sup>++</sup>
	146	DE	DE 2 513 797		Imperial Chemical Industries (see Doc. No. 14)	10/9/1975		X <sup>+</sup>
	147	DE	DE 2 938 807		Green Cross Corp.	11/13/1980		X <sup>+</sup>
	148	DE	DE 3 421 468		Dr. Rentschler Arzneimittel GmbH & Co. (see Doc. No. 80)	12/19/1985		X <sup>+</sup>
	149	EP	EP 0 052 322		Gersonde, Klaus (see Doc. No. 129)	5/26/1982		X <sup>+</sup>
	150	EP	EP 0 193 208		Technicon Instruments Corp.	9/3/1986		
	151	EP	EP 0 272 091		Vestar, Inc.	6/22/1988		
	152	EP	EP 0 330 532		Fournier Industrie (see Doc. No. 81)	8/30/1989		X <sup>+</sup>
	153	EP	EP 0 391 369		Yissum Research Development Company of the Hebrew University of Jerusalem	10/10/1990		
	154	EP	EP 0 418 153		Medgenix Group, S.A. (see Doc. No. 87)	3/20/1991		X <sup>+</sup>
	155	EP	EP 0 456 670		B. Braun Melsungen AG	11/21/1991		X <sup>+</sup>
	156	EP	EP 0 456 764		B. Braun Melsungen AG	11/21/1991		X <sup>+</sup>
	157	EP	EP 0 499 299		Sterling Winthrop Inc.	8/19/1992		
	158	EP	EP 0 570 829		Dietl, Hans, Dr. (see Doc. No. 104)	5/12/1993		X <sup>+</sup>
	159	EP	EP 0 580 690		Sandoz, Ltd.	2/2/1994		
	160	EP	EP 0 602 700		Sterlig Winthrop, Inc.	6/22/1994		
	161	EP	EP 0 724 877		Laboratories Fournier S.C.A. (see Doc. No. 130)	8/7/1996		X <sup>+</sup>
	162	EP	EP 0 757 911		CL Pharma (see Doc No. 124)	2/12/1997		X <sup>+</sup>
	163	EP	EP 0 605 497		Muller, Rainer	3/20/1996		
	164	FR	FR 2 617 047		Laboratories Fournier	3/20/1996		X <sup>+</sup>
	165	GB	GB 1 527 638		Bayer Aktiengesellschaft	10/4/1978		
	166	GB	GB 2,046,094		Technicon Instruments Corp.	9/3/1986		
	167	HU	HU 211 580B		F.GIS (see Doc. No. 89)	6/20/1995		X <sup>+</sup>
	168	JP	JP1502590		A. Nattermann & Cie (see Doc. No. 176)	11/12/1980		X <sup>+</sup>
	169	JP	JP55141407		A. Nattermann & Cie (see Doc. No. 31)	11/5/1980		X <sup>+</sup>
	170	JP	JP 56167616		Green Cross Corp. (see Doc. No. 40)	5/15/1980		X <sup>+</sup>
	171	JP	JP60208910		A. Nattermann & Cie	11/5/1980		X <sup>+</sup>

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				Application Number	09/321,766	
				Filing Date	May 28, 1999	
				First Named Inventor	Awadhesh K. MISHRA	
				Group Art Unit	1617	
Examiner Name	E. J. Webman					
Attorney Docket Number	401730/SKYEPhARMA					
Sheet	6	of	8			


FOREIGN PATENT DOCUMENTS								
Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No**
	172	JP	JP63233915		Green Cross Corp. (see Doc. No. 96)	10/21/1985		X <sup>+</sup>
	173	JP	JP63502117		Liposome Technology, Inc. (see Doc. No. 175)	8/13/1987		X <sup>+</sup>
	174	WO	WO 85/00011		University of Miami	1/3/1985		
	175	WO	WO 87/04592		Liposome Technology, Inc.	8/13/1987		
	176		WO 88/04924		Liposome Technology, Inc.	7/14/1988		
	177	WO	WO 91/04011		Riker Laboratories, Inc.	4/4/1991		
	178	WO	WO 00/10531		RTP Pharma, Inc.	3/2/2000		
	179	WO	WO 00/30616		RTP Pharma, Inc.	6/2/2000		
	180	WO	WO 00/40219		Dexcel, Ltd.	7/13/2000		
	181	WO	WO 00/41682		LG Chemical, Ltd.	7/20/2000		
	182	WO	WO 01/30372		Bask Aktiengesellschaft	5/3/2001		
	183	WO	WO 92/18105		Sandoz, Ltd.	10/29/1992		
	184	WO	WO 94/20072		Pharmacia AB	9/15/1994		
	185	WO	WO 96/21439		Galephar P.R., Inc.	7/18/1996		
	186	WO	WO 96/24332		Nanosystems, LLC	8/15/1996		
	187	WO	WO 97/14407		Research Triangle Pharmaceuticals	4/24/1997		
	188	WO	WO 99/29300		RTP Pharma, Inc.	6/17/1999		
	189	WO	WO 99/29316		Cyclosporine Therapeutics, Ltd.	6/17/1999		
	190	WO	WO 99/49846		RTP Pharma, Inc.	10/7/1999		
	191	WO	WO 99/49848		RTP Pharma, Inc.	10/7/1999		

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							Yes	No**
	192	ROSS et al., "Aqueous Solutions of Surface-Active Solutes", <i>Colloidal Systems and Interfaces</i> , © 1988, pp. 148-151						
	193	SANDE et al., "Antimicrobial Agents: Antifungal and Antiviral Agents", pp. 1219-1222						
	194	BITTMAN, ROBERT, "Sterol-Polyene Antibiotic Complexation: Probe of Membrane Structure," <i>Lipids</i> , Vol. 13, No. 10, pp. 686-691 (1978).						
	195	MISHRA et al., "Scientifically Speaking: Novel Injectable Formulations of Water-Insoluble Drugs", <i>Controlled Release Newsletter</i> , Vol. 17, Issue 2, (June 2000), pp. 21-30						
	196	BANGHAM et al., "Diffusion of Univalent Ions Across the Lamellae of Swollen Phospholipids", <i>J. Mol. Biol.</i> (1965) 13, pp. 238-252						
	197	HUANG et al., "Interaction of the N-terminus of Sterol Carrier Protein 2 with Membranes: Role of Membrane Curvature", <i>Biochem. J.</i> (1999) Vol. 8, pp. 593-603						

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			First Named Inventor	Awadhesh K. MISHRA	
			Group Art Unit	1617	
Examiner Name	E. J. Webman				
Sheet	7	of	8	Attorney Docket Number	401730/SKYEPhARMA

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			Yes	No**
	198	GREGORIADIS, GREGORY, "The Carrier Potential of Liposomes in Biology and Medicine", <i>New Engl. J. Med.</i> , (1976) Vol. 295, No. 13, pp. 704-710		
	199	CUDD et al., "Liposomes Injected Intravenously into Mice Associate with Liver Mitochondria," <i>Biochem. Biophys. Acta</i> , (1984) Vol. 774, pp. 169-180		
	200	BENZ et al., "Electrical Capacity of Black Lipid Films and of Lipid Bilayers Made from Monolayers", <i>Biochem. Biophys. Acta</i> , (1975) Vol. 394, pp. 323-334		
	201	GOODMAN and GILLMAN'S, "The Pharmacological Basis of Therapeutics," 7 <sup>th</sup> Ed., <i>MacMillan Publishing Co.</i> , New York (1985) Chap. 15, p. 312		
	202	CHERNEY, L.S., "Tetracaine Hydroiodide: A Long Lasting Local Anesthetic Agent for the Relief of Postoperative Pain", <i>Anesth. Analg.</i> (1963) Vol. 42, No. 4, pp. 477-481		
	203	HAYNES et al., "Metal-Ligand Interactions in Organic Chemistry and Biochemistry", <i>B. Pullman and N. Goldblum (eds.)</i> , part 2, (1977), pp. 189-212		
	204	HAYNES et al., "Ultra-Long Duration Local Anesthesia Produced by Injection of Lecithin-coated Methoxyflurane Microdroplets", <i>Anesthesiology</i> (1985) Vol. 63, No. 5, pp. 490-499		
	205	HAYNES et al., "Ultra-Long Duration Local Anesthesia Produced by Intra-Dermal Injection of Lecithin-Coated Methoxyflurane Microdroplets", <i>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</i> , (1987) Vol. 14, pp.293-294		
	206	KIRKPATRICK et al., "Local Anesthetic Efficacy of Methoxyflurane Microdroplets in Man," <i>Anesthesiology</i> (1987) 67(3A): A254		
	207	GENNARO et al., "Sustained-Release Drug Therapy," <i>Remington's Pharmaceutical Sciences</i> , 17 <sup>th</sup> Ed., (1985), p. 1645		
	208	"Derived Diameters and Distribution Statistics," from an unknown web-site, 6 pages		
	209	"Getting Started", Man 0106, Issue 1.0, (Jan. 1996), <i>Malvern Instruments Ltd.</i> , England, pp. 7.1-7.7		
	210	CHULIA et al., Powder Technology and Pharmaceutical Processes, (1994), pp. 66-67.		
	211	HERBERT A. LEIBERMAN and LEON LACHMAN, Eds., <i>Pharmaceutical Dosage Forms, Tablets</i> , Vol. 1, (1980), p. 13		
	212	MIYAJIMA, KOICHIRO, "Role of Saccharides for the Freeze-Thawing and Freeze-Drying of Liposome", <i>Advanced Drug Delivery Review</i> , Vol. 24, (1997), pp. 151-159		
	213	BUCHMULLER et al., "Cryopel: Ein neues Verfahren zum Pelletieren und Frosten Biologischer Substrate," <i>Gas Aktuell</i> , 35, 1(1989), pp. 10-13		X
	214	WU et al., "Pharmacokinetics of Methoxyflurane After Its Intra-Dermal Injection as Lecithin-Coated Microdroplets," <i>Journal of Controlled Release</i> , (1989), Vol. 9, pp. 1-12		
	215	PACE et al., "Novel Injectable Formulations of Insoluble Drugs", <i>Pharmaceutical Technology</i> , Vol. 23, No. 3, (March 1999), pp. 116-134		
	216	ROMPP'S CHEMIE LEXIKON, 2 Aufl., Bd. 1, (1950), Stichwort, "Emulsion"		X
	217	BERGMANN, LUDWIG, <i>Der Ultraschall</i> , 5 Aufl., (1949), Stuttgart, S. 551-564, 672f		X
	218	LEHNINGER BIOCHEMISTRY, "The Molecular Basis of Cell Structure and Function", (1970) Chapter 10		

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			Yes	No**
	219	GUZMAN et al., Formation and Characterization of Cyclosporine-Loaded Nanoparticles, 1088 J. Pharm. Sci 82 (1993) No. 5 pp. 498-502		
	220	NAPPER, DONALD, "Polymeric Stabilizations of Colloidal Dispersions", (1983)		
	221	MULLER et al., Emulsions and Nanosuspension, Chap. 9 (1998) p. 163		
	222	LOURENCO et al., "Steric Stabilization of Nanoparticles: size and Surface Properties", <i>Int. J. of Pharm.</i> , Vol. 138 (1996), pp.1-12		
	223	LUCKHAM, PAUL F., "The Physical Stability of Suspension Concentrates with Particular Reference to Pharmaceutical and Pesticide Formulations", <i>Pestic Sci.</i> , 1989, Vol. 25, pp. 25-34		
	224	CALVOR et al., Production of Microparticles by High Pressure Homogenization", <i>Pharm. Dev. Tech.</i> , 1998, Vol. 3(3), pp. 297-205		
	225	[LSP4]LA FUMA Polymery, "The Role of Water-soluble Polymers at the Solid/liquid Interface in the Mechanisms of Flocculation/stabilization of Aqueous Colloidal Suspensions", 1998 43 nr 2, pp. 104-108		
	226	SEIKMANN et al., "Melt-homogenized Solid Lipid Nanoparticles Stabilized by the Non-ionic Surfactant Tyloxapol", <i>Pharm. Pharmacol Lett</i> , 1994, Vol. 3, pp. 225-228 *		
	227	FREITAS et al., "Spray-drying of Solid Lipid Nanoparticles (SLNtm)," <i>European Journal of Pharmaceuticals and Biopharmaceuticals</i> , 46, 1998, pp. 145-151.		
	228	KAWASHIMA et al., "Preparation of Powdered Phospholipid Nanospheres by Spray Drying in a Aqueous System with Sugars," <i>Chem. Pharm. Bull.</i> , 40(7), 1992, pp. 1911-1916.		

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